

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim Amendments

Claims 2, 9, 10 and 12 have been cancelled, without prejudice or disclaimer.

Consideration After Final Rejection

Although this amendment is presented after final rejection, the Examiner is respectfully requested to enter the amendments and consider the remarks, as they place the application in condition for allowance.

Patentability Arguments

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Discussion Regarding Applicants' Invention

Applicants' claims recite a method for manufacturing a processed cheese having angiotensin converting enzyme inhibitory activity of 350 units/gram or more, comprising processing a raw material comprising at least one type of natural cheese having angiotensin converting enzyme inhibitory activity of 420 units/gram or more. [Independent Claim 5]

Applicants' claimed method has the following advantages:

(1) Consumption of 10 to 15 grams/day of Applicants' processed cheese results in intake of total angiotensin converting enzyme (ACE) inhibitory activity of 5000 units. This is considered to be effective in sustaining a normal blood pressure.

The average amount of cheese consumed by a Japanese person is about 5.5 grams/day. It has been determined, for the first time, that the ACE inhibitory activity of currently marketed processed cheese is, at most, around 200 units/gram. (Please see Table 1 on page 2 of Applicants' specification.) Thus, in order to reach the ACE inhibitory activity which would

sustain a normal blood pressure (as discussed above), 25 grams/day of currently marketed processed cheese must be consumed. This is clearly much higher than the average amount of cheese consumed by a Japanese person in a day. Thus, it would be difficult for a Japanese person to seek a sustained blood pressure by consumption of a currently marketed processed cheese.

Applicants have measured ACE inhibitory activities of various kinds of natural cheeses, and discovered that natural cheese having a high ACE inhibitory value and natural cheese having a low ACE inhibitory value exist.

Applicants have discovered a method of manufacturing a processed cheese having an ACE inhibitory activity of 350 units/gram or more by selecting and processing a raw material comprising at least one type of natural cheese having an ACE inhibitory activity of 420 units/gram or more. By employing Applicants' method, a processed cheese having a high ACE inhibitory activity (compared to the currently marketed processed cheese) is made, and 5000 units of total ACE inhibitory activity (the amount considered effective in sustaining a normal blood pressure) may be obtained by consuming around 10 to 15 grams of processed cheese per day.

Rejections Under 35 U.S.C. § 102(b)

Draaisma et al. (U.S. 2002/0182301)

The rejection of claim 2 under 35 U.S.C. § 102(b) as being anticipated by Draaisma et al. (U.S. 2002/0182301) has been rendered moot by the cancellation of claim 2.

Henson (WO 97/18718)

The rejection of claims 2, 5-10 and 12-16 under 35 U.S.C. § 102(b) as being anticipated by Henson (WO 97/18718) is respectfully traversed for the reasons discussed on pages 6 and 7 of this response.

JP 2003-033136 (Machine Translation)

The rejection of claims 2, 5-10 and 12-16 under 35 U.S.C. § 102(b) as being anticipated by JP 2003-033136 is also respectfully traversed for the reasons set forth on pages 6 and 7 of this response.

The Position of the Examiner

The Examiner takes the position that Henson discloses natural aged cheese, which inherently has ACE inhibitory activity of 420 u/g or more as presently claimed, thus resulting in a processed cheese having ACE inhibitory activity of 350 u/g or more.

Similarly, the Examiner asserts that since JP '136 discloses processing natural cheese as presently claimed, as well as using a cheese identical to that used in the present invention, i.e. New Zealand cheddar, it is clear that the natural cheese, used as raw material, would inherently have ACE inhibitory activity of 420 u/g or more as presently claimed, and the processed cheese would inherently have ACE inhibitory activity of 350 u/g or more as presently claimed.

Applicants' Arguments

Applicants respectfully disagree with the Examiner's position for the following reasons.

The Examiner's rejections are based upon inherency, i.e., that the cheeses (natural and processed) of the references inherently have Applicants' recited ACE inhibitory activities.

MPEP 2112 states that "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) ... 'To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)." (Emphasis added.)

Applicants respectfully note that not all kinds of processed cheese disclosed in Henson and JP '136 necessarily have ACE inhibitory activities of 350 u/g or more. Accordingly, for the reasons set forth in MPEP 2112, a rejection based upon inherency is improper.

As shown in Table 2 of Applicants' specification (pages 6-7), not all kinds of natural cheese necessarily have high ACE inhibitory activities, i.e., 420 u/g or more. When a natural cheese with low ACE inhibitory activity is used as a raw material, it is impossible to produce a processed cheese having ACE inhibitory activity of 350 u/g and more, as required by Applicants' claims. Accordingly, processing a natural cheese as taught in either Henson or JP '136 does not necessarily result in a processed cheese with Applicants' recited ACE inhibitory activity.

The Examiner asserts that since aged cheese (Henson) and New Zealand cheddar cheese (JP '136) inherently have the recited ACE inhibitory activity, then a processed cheese resulting there from would have Applicants' recited ACE inhibitory activities, and therefore, Applicants' claimed process is anticipated. However, neither of the cited references even mention ACE inhibitory activities. [In fact, the Examiner has relied upon Applicants' own disclosure as evidence that the cheese of JP '136 has a particular ACE inhibitory activity.] Thus, neither reference recognizes the need for, or importance of processing a natural cheese with the recited ACE inhibitory activity. Additionally, neither of the references teaches, or even suggests, selecting a cheese with a particular ACE inhibitory activity (420 u/g or more), and processing said cheese to obtain a processed cheese with a particular ACE inhibitory activity (350 u/g or more).

Accordingly, neither of the references teaches each and every limitation of Applicants' claimed method, wherein a raw material comprising at least one type of natural cheese having ACE inhibitory activity is selected and processed to obtain a processed cheese having ACE inhibitory activity of 420 u/g. Accordingly, it is respectfully requested that the above rejections be withdrawn.

Conclusion

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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